PUBLIC HEALTH FOUNDATION OF INDIA (PHFI)

LIMITED TENDER

Tender Number: PHFI/Research/UDAY/2018/004 (Re)

REQUEST FOR PROPOSAL (RFP)

FOR SELECTION OF VENDOR FOR COLLECTION, PROCESSING, ANALYSIS AND TRANSPORTATION OF BIO-SAMPLES AT SONIPAT

APRIL 2018

Call for Tender Launching: May 14, 2018 by 5.00 PM
Last date of submission of Bid: May 25, 2018 by 5.00 PM

Public Health Foundation of India

Plot No. 47, Sector-44 Institutional Area, Gurgaon-122002, Haryana

Tel +91 124-4781400 | **Web** www.phfi.org

Project office:
Public Health Foundation of India
First Floor, House Number 2349, Sector -15,
Sonipat- 131001, Haryana

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1. INTRODUCTION

1.1. Purpose of call for Proposal

(a) The purpose/intent for this invitation is to collect bio-samples (14 ml of blood and 40 ml of urine) from approximately 5000 participants of baseline survey under project UDAY. The survey will be conducted in the rural and urban sites of Sonipat (Haryana). We invite agencies to submit a detailed project proposal to conduct the exercise.

(b) This Request for Proposals (RFP) must be in the format as mentioned in this RFP. Agencies are required to submit a detailed proposal clearly indicating their plan for, i) collecting the fasting blood and first void urine samples from the participants of the end line survey in their households, ii) transporting the samples from the field to the local laboratory in Sonipat, iii) processing of blood and urine samples as per protocol, iv) analysis for fasting plasma glucose (mg/dl), hemoglobin (g/dl) and urine protein and sugar using dipsticks, iv) transporting the aliquots of the samples from the local laboratories to PHFI office in Gurgaon, Haryana. The proposal submitted by agencies will be reviewed by PHFI Evaluation Committee to be formed for this purpose. Agencies submitting proposals with clearly defined methodology, quality assurance including technical expertise would be given preference especially those who have had prior experience. Two or more agencies can jointly bid for the project.

1.2. Background of the Study

The Public Health Foundation of India (PHFI) aims to strengthen the capacity for training, research, and policy development in public health in India. PHFI together with partners, has been implementing Project UDAY at Sonipat. Under UDAY, end line survey is being planned and, in the survey, bio samples from approx. 5000 participants (± 5% of the number quoted) will be collected in their households.

1.3. Key Dates

Schedule of Tender Processing (Key Dates)

	Tender Inviting Authority	**Public Health Foundation of India PLOT No. 47, Sector-44, Institutional Area, Gurgaon-122002,**	
Sl. N	**Description**	**Date**	Time
1.	RFP released on PHFI Web Site	May 14, 2018	By 5.00 PM
2.	Last date for receiving Queries from Agencies, if any	May 19, 2018	By 11.00 AM
3.	Last date for submission of Bids	May 25, 2018	By 5.00 PM
4.	Opening of Tender Box and Technical Bids (Authorized representatives of Agencies may be present for opening of Tender Box)	May 28, 2018	At 10.00 AM
5.	Intimation to the Agencies who qualify in the Technical Bids	May 28, 2018	By 5.00 PM
6.	Interview of Qualifying Agencies (Format will be intimated through PHFI Tender email to concerned Agencies)	May 29, 2018	9:30 AM to 11:30 PM
7.	Opening of Financial Bids of Technically Qualified Agencies (Authorized representative may be present)	May 29, 2018	12.00 pm to 01:00 pm
8.	Interview cum Financial Negotiation with the short-listed agency	May 29, 2018	3.00 PM to 4.00 pm
9.	Issue of Letter of Intent/Award	As per the decision of the PHFI Management	

2. QUALIFICATION/ELIGIBILITY CRITERIA

The qualification/eligibility criteria for the agency are given below.

Sl. No	Qualification Criteria	Proof Required
1	I. Name and address of the agency II. Year of establishment	Copy of Certificate of Incorporation/ Registration/MoU as applicable
2	Whether the agency is registered under Society Registration Act or is an autonomous body or a Limited company or partnership firm, etc. and details thereof (e.g.-name (s) of partners, Managing Directors, Chief Executive Officers, Key authorized persons)	
3	The agency should have a valid PAN and Service Tax Registration in India	Copy of PAN card and Service Tax Registration
4	The agency should have a minimum average annual turnover of INR Forty Lakhs during the last three fiscal years	Copy of Audited Profit and Loss Statement and Balance Sheet
5	The agency may have an experience of collecting bio-samples from participants of survey	Necessary documents as evidence.
6	The agency should not have been blacklisted by Central/State Government departments/Undertakings	No conviction certificate duly signed by the authorized signatory of the
7	**Previous experience of work with PHFI**	1. **Name of Project & Department of PHFI sponsoring the RFP (Tender No & Date)** 2. **Reference & Date of Service Agreement** 3. **Date of Commencement & Date of Completion (Whether completed as per Time Line)** 4. **Value of the Project** **Any comments on the conduct of the Project**

3. Terms of References (TORs) and Deliverables

3.1. Details of TORs to be prepared under the proposal

The following activities are to be carried out in consultation with PHFI.

The agency shall collect, store when required and transport the biological samples (blood and urine) collected from the selected approx. 5000 persons (2500 in urban Sonipat and 2500 in rural Sonipat [Kharkhoda block] Haryana) as per the following terms and conditions:

1 The agency shall use enough numbers of trained phlebotomists to collect biological samples (blood and urine) of about 30 to 50 persons per day each in urban Sonipat, and villages of Kharkhoda block in rural Sonipat.
2 As the study requires collecting fasting blood samples and first morning void urine, all samples shall be collected early morning (5 am to 9 am) during the study period, six days a week including Sundays, by trained phlebotomists.
3 All samples shall be carefully labelled with sample IDs.
4 After collection of the biological samples in the households, the samples shall be stored in the cool containers within stipulated temperature, i.e. between 2 to 8^{o} Celsius or freezing according to the standard guidelines, to maintain the cold chain and then transported to the designated lab in Sonipat as soon as possible.
5 The agency shall analyze the fasting blood glucose and hemoglobin on the same day for all the selected participants and reports will be provided by PHFI on their letterhead on next day through UDAY health workers.
6 The agency shall transport the processed aliquots to the central lab of PHFI situated in Delhi NCR, under strict cold chain maintenance within 24 to 48 hours of the collection.
7 All the Material and Manpower required for collection, processing, temporary storage, analysis and transportation of biological samples (blood and urine) to the PHFI lab shall be purchased/arranged by the agency.
8 The laboratory agency shall use high quality material as agreed with PHFI lab manager for the collection, local transport, analysis, processing and transporting the biological samples to PHFI lab in Gurgaon.
9 Sample ID (stickers) for labelling of the biological samples shall be provided by PHFI office at Sonipat.
10 The agency shall allow PHFI staff to supervise the collection of bio samples.
11 The agency shall designate a point person for coordinating and reporting on daily basis with the Lab technician in Sonipat.

The detailed protocol given in annexure 1.

4. IMPLEMENTATION SCHEDULE/TIME LINES

The work would be aligned with the end line survey of UDAY. It is expected that the survey will be completed in 6 months.

5. PERFORMANCE BANK GUARANTEE

5.1. The successful final selected organization shall have to submit a Performance Bank Guarantee within 30 (thirty) days from the date of issue of Service Agreement. Extension of time for submission of PG beyond 30(thirty) days and up to 60 days from the date of issue of Service agreement may be given by the Authority who is competent at PHFI. However, a penal interest of 24% per annum shall be charged for the delay beyond 30(thirty) days i.e. from 31st day after the date of issue of Service Agreement. In case the organization fails to submit the requisite PG even after 60 days from the date of issue of Service Agreement, the contract shall be terminated.

5.2. **The successful organization shall submit the PBG matching with the First Advance payment.**

5.3. The PBG will be valid till completion of the project period and shall be released only after 60 days of physical completion of the work based on Satisfactory Completion Certificate issued by the PI stating that the organization has completed the work in all respects satisfactorily.

6. PAYMENT SCHEDULE

Terms of Payment will be decided with agency at the time of Final Interview & Negotiation**.**

7. GUIDELINES FOR SUBMITTING PROPOSAL

7.1. Preparing the Technical Proposal

The agency is required to submit a technical proposal.

7.1.1. Technical Proposal Submission Format:

The proposal should follow the format given below (but not necessarily limited to the following) and should be in English and formatted on standard A4 paper with single space, 12 point font Times New Roman and each page numbered consecutively. The proposal should capture the following information, with a maximum of 20 pages:

The plan to a) collect the samples, the items used for collection, processing, analysis, temporary storage and transport, b) technical specification of the items used for collection (vacutainer, cryovial, cryoboxes brand, volume etc.), local transport, processing, analysis, temporary storage, and transport to PHFI lab c) number of phlebotomists employed, qualification and experience of phlebotomists, training of phlebotomists, d) transport samples collected in the field to the local laboratory, e) plan of processing of samples, f) plan to analyse the sample for fasting blood glucose and Hemoglobin estimation, g) printing of report h) transport of aliquots in cryovials, cryoboxes from the local lab to PHFI Gurgaon under cold chain, whether data logger will be used to record temperature during transport to PHFI Gurgaon.

7.1.2. Institution/ Organization/ Consulting Agency profile

a. Name and address of the agency.
b. Year of establishment.
c. Legal status of the agency – Whether agency is registered under the Societies Registration Act or is an autonomous body or a Limited company or partnership firm, etc. and details there of (e.g. – name(s) of partners, Managing Directors, Chief Executive Officers, key authorized person)
d. Principal nature of activities undertaken.
e. Details of manpower as prescribed above.
f. Communication details of the agency: mailing address, telephone and fax numbers, email address, etc.

7.1.4. Financial Status of the Organization

a. Total revenue and expenditure of the organization for the past three fiscal years.
b. Copies of the certified Audited Annual Accounts in support of the Financial status.

7.1.5. Income Tax Details

Whether the agency is exempted from Income Tax? If yes, please furnish the exemption certificate number and date up to which exempted. A copy of exemption certificate is to be attached. If no, furnish PAN/TAN number, the copy of the latest Income Tax returns and assessment order.

7.2. Preparing the Financial Proposal

(i) The Financial Quotes should cover the following:

- entire cost of activity listed in the terms of reference;
- personnel to be involved including number, their time commitment, unit cost, and overall personnel costs;
- travel costs
- material cost (vacutainers, needles, swabs etc.)
- communication costs;
- any other reasonable cost which the agency might incur

(ii) The total cost quoted should be inclusive of all taxes.

(iii) The financial proposal will be evaluated only if a field agency qualifies based on the assessment of the Technical proposal.

7.3. Submission of Bids

(i) The Bidder shall submit a sealed cover consisting of these two sealed envelopes with a clear label for each:

i. Technical Proposal, super scribing on the right hand side top of the cover as Technical Bid (2 copies).
ii. Financial Proposal super scribing on the right hand side top of the cover as Financial Bid (2 copies).

(ii) All the pages of the Financial Proposal shall be duly signed by the Authorized Signatory of the Bidder before submission. Corrections, if any shall be counter signed.

7.4. General Instructions and Terms and Conditions

a. The proposal along with all the correspondence and documents exchanged by the agency and PHFI shall be written in English language.

b. **Amendments to the Tender:** Tender Committee at PHFI reserves every right to amend any of the Tender conditions or a part thereof, before the last date for the receipt of the Tender, if necessary. Amendments, if any, would be put on the website. The decision of extending the due date and time for the submission of Tender documents on account of amendments will be the sole discretion of PHFI.

c. **Reserved Rights:** PHFI reserves the following rights with regard to this call for proposal:

- To cancel this call for proposal at any stage without assigning any reason.
- To disqualify any Applicant(s) based on Applicant(s) failure to follow solicitation instructions
- PHFI reserves the right to waive any deviations by Applicants from the requirements of this solicitation that in PHFI 's opinion are considered not to be

material defects requiring rejection or disqualification; or where such a waiver will promote increased competition;

- Extend the time for submission of all RFP responses after notification to all Applicants;
- Terminate or modify the RFP process at any time and re-issue the RFP to whomever PHFI deems appropriate;
- PHFI reserve the right to select and negotiate with those applicants it determines, in its sole discretion, to be qualified for competitive proposals and to terminate negotiations without incurring any liability;
- PHFI reserves the right to negotiate the fee or issue an award based on the initial evaluation of Applicants without discussion;
- Award only part of the activities in the solicitation or issue multiple awards based on solicitation activities.

d. No proposal shall be accepted unless it is properly sealed. Agency shall not be allowed to fill in or seal their proposal at the PHFI office. The documents should be sent by speed post/registered post/courier or hand delivered.

e. If the envelope is found to be open, not sealed and not marked as instructed above, PHFI will not be responsible for misplacement or premature opening of the proposal submitted. Any proposal opened prematurely due to this cause shall be rejected.

f. The bidder is advised to attach any additional information that is considered necessary in regard to establish the capabilities. No further information will be entertained after submission of application unless it is required by PHFI. PHFI, however, reserves the right to call for additional information and clarification on information submitted by the bidders.

g. Proposals must be received by PHFI at the address specified not later than the date and time specified in the Invitation of RFP. In case the specified date for the submission of proposal being declared holiday by the PHFI, the same will be received on next working day with the same specified time. Proposals received after the due date and time specified will automatically be rejected.

h. **Withdrawal of Proposals:** Applicants may withdraw proposal by written notice via email received at any time before contract. Proposals may be withdrawn in person by an offer or his/her authorized representative, if the representative's identity is made known and the representative signs a receipt for the proposal before award.

i. **Opening of Tenders:** Sealed Tenders received up to **May 25, 2018 5.00 PM** will be taken

up for opening. Tenders received after specified date and time will not be accepted. PHFI reserves the right to disqualify any of the tender in case it is not satisfied with the documents furnished or otherwise without assigning any reasons thereof. The Technical proposals will be opened on **May 28, 2018 10.00 AM** at PHFI, address as mentioned. A representative from each Bidder is invited to be present. The Financial proposals of those Agencies qualifying on the basis of the assessment of Technical proposals will be opened on **May 29, 2018 12.00 PM** at PHFI, address mentioned above. A representative from each qualifying Bidder may be present.

j. Any efforts by agency to influence the PHFI personnel or representatives on matters relating to proposals under study in the process of examination, clarification, evaluation and comparison of proposal and in decision concerning award of contract, shall result in the rejection of the agency's proposal. Failing to execute the contract Agreement within the said period may result in termination of contract and award of the same to other agency/ agencies at the risk and cost of the agency.

k. The person to sign the contract agreement shall be duly authorized.

l. The RFP shall not bind PHFI in any way whatsoever to offer any job to the applicant if it is decided to abandon the study.

m. PHFI assures that the documents and presentations by the applicants will be kept strictly confidential and will not be used for any purpose other than the process of selection of the final applicant. All documents created/prepared during the assignment by the selected application shall be the property of PHFI and they will have the rights associated with such documents.

n. **Offer Verification:** PHFI may contact applicant to confirm contact person, address, bid amount and to confirm that the bid was submitted for this solicitation.

o. **Conflict of Interest:** Applicants must provide disclosure of any past, present or future relationships with any parties associated with the issuance, review or management of this solicitation and anticipated award. Failure to provide full and open disclosure may result in PHFI having to re-evaluate selection of potential Applicants.

p. **Arbitration:** Should any dispute arise, it may be referred to an Arbitrator appointed by mutual consent. The place of Arbitration shall be New Delhi.

q. The cost of travel and stay of the officials from the agency for attending meetings with PHFI will be met by the respective agency.

r. **All queries/correspondences pertaining to this RFP will be done through PHFI Tender email i.e. tenders@phfi.org**

Hard copies of the Proposals should be addressed to:

The Chairperson Tender Committee
RFP: FOR SELECTION OF VENDOR FOR COLLECTION AND TRANSPORTATION OF BIO-SAMPLES AT SONIPAT
Public Health Foundation of India
First Floor, House No. 2349,
Sector-15
Sonipat – 131001.

The last date for submission of complete Proposal with all supporting documents (by hand or by post) is **May 25, 2018 5.00PM.** Any Proposal received after this prescribed time will not be entertained. PHFI will not be responsible for any loss in transit or postal delay.

8. EVALUTION OF PROPOSAL

8.1. Evaluation Committee

An Evaluation committee formed by PHFI would first examine the bids based on the details provided in the Invitation for proposal for those agencies who are short listed as per the qualification criteria. For final evaluation, Evaluation Committee shall take into consideration the financial proposal. The Applicants who submits the lowest quote will be awarded the project cure minimum Technical qualifying marks as mentioned in paras below.

8.2. Selection of Institution/ Organization/ Consulting Agency

a. An agency is required to score a minimum qualifying marks of 70 points out of 100, which will be recalibrated out of 60 in the technical proposal in order to qualify for Interview and financial bid opening.

b. Financial bid of agency will be opened only if the agency qualifies in the Technical evaluation (score of a minimum of 70 points).

c. For the Final evaluation, the weightage for the Technical proposal, Interview and Financial proposal would be 60%, 20% and 20%, respectively.

d. PHFI shall reserve the right to negotiate with the Bidder whose proposal has been

ranked first by the Committee on the basis of Technical and Financial evaluations and the Interview.

e. The submitted proposals will be valid for 60 days from the date of submission. PHFI will make its best effort to select the Institution/ Organization/ Consulting Agency within this period.

8.3. Technical Evaluation (60)

Technical evaluation shall be carried out based on the following:

Sr No.	Evaluation Criteria	Maximum Score
1	Technical approach	40
2	Experience in carrying out large research projects	20
3	Management plan	10
4	Past performance and organizational capacity	30
	Total score	**100 (will be recalibrated out of 80)**

i. Technical Approach: (60 points)

A technical approach that is well-conceived, planned and result-oriented, which demonstrates a clear understanding of the task will be scored high. The technical approach should describe the work flow chart along with a clear implementation plan, roles and responsibilities of the team, deliverables and timelines for accomplishing each job description.

ii. Experience in conducting large research projects: (30 points)

This section should clearly describe the applicant's and its staff's experience in managing similar tasks along with other assignments involving surveys of public health/social science. The application should clearly mention the specific projects that have been undertaken at the national / state level including the names of national or international clients/organizations, value (cost) of the projects and timelines.

iii. Management Plan: (10 points)

The Management Plan will be evaluated based on its ability to achieve results. It must consist of a clear and concise description of how internal management plans, organizational structures, lines of communication are conducive to effective project implementation. The management plan should also explain the internal monitoring systems and quality assurance mechanisms.

8.5. Financial Evaluation (20)

Financial evaluation shall be carried out based on the following:

Cost will primarily be evaluated for reasonableness, realism, allowability and the applicant's understanding of the work to be performed. Effective cost saving measures to improve cost efficiency of the project will also be considered. Applications that demonstrate realistic scenario to accomplish the job in a time-bound manner with minimal resources would be considered.

Full marks will be awarded to the lowest qualifying bidder. For subsequent bidders the marks will be a ratio of the lowest bidder. If the lowest bid is "X" and bid for "Y" needs to be evaluated then its marks will be "highest mark x (X/Y)" Once the agency is finalized, additional information and discussion will occur between the applicant and PHFI during development of detailed Technical proposal.

9. CONTACT FOR MORE INFORMATION

For all correspondence please refer to PHFI general tender Email: tenders@phfi.org with subject line marked as ""

END OF RFP

DISCLAIMER:

This EOI represents only a definition of requirements. It is merely an invitation for submission of concept paper and does not legally obligate PHFI to accept any of the submitted EOI in whole or in part, nor is PHFI obligated to select the lowest priced proposal. PHFI reserves the right to negotiate with any or all applicants, both with respect to price, cost and/or scope of services. PHFI has no contractual obligations with any offer or based upon issuance of this RFP. It is not an offer to contract. Only the execution of a written contract shall obligate PHFI in accordance with the terms and conditions contained in such contracts.

Annexure 1: Bio-sample processing protocol

Specimen collection

Biological specimens to be collected for the study:

- 14 ml of blood
- 40 ml of urine (early morning void)

After the specimens are collected, the lab technician will complete a specimen collection form and transport the specimens to the laboratory for processing. The blood tubes will be processed for serum, plasma, buffy coat and red blood cells (RBC). **Analysis for plasma glucose and haemoglobin estimation will take place same day of collection**. Serum, whole blood and other aliquots will be stored in deep freezer for transportation to New Delhi lab. Urine samples will be tested for protein & sugar by dipsticks on the same day. Remaining urine will be aliquoted into vials and will be stored for transportation to New Delhi.

Labelling of bio-specimens

Assigning codes: Each specimen collected during the study will be identified with a unique sample ID (SID) number. This will be X digit numeric code. Sample ID will be used to identify the unique specimens. The Sample IDs will be printed on labels that are freezer safe.

Assigning a Sample ID

Each participant who enrolls into this study will be assigned a Sample ID. These SIDs will be used when a specimen collection kit is assigned to a participant.

Pre-labeling of collection materials: All collection materials for blood (Vacutainer tubes -one red top, one grey top and one lavender top) and sterile container for urine will be pre-labeled with Sample ID. Extra labels will be provided in the specimen collection kit to be used in case of damage to any of the printed labels. The extra labels to label replacement materials will be provided. Only these specific labels should be used to label replacement collection materials.

Blood collection

Collection kit: One specimen collection kit is used for each blood sample. Each specimen collection kit contains the key items required for blood collection. As much as possible, protect tubes from extreme temperatures by storing the kits in a cool place.

The following items for blood collection are included in the specimen collection kit:

- One 6.0 ml lavender-top Vacutainer tubes
- One 6.0 ml red-top Vacutainer tube
- One 2.0 ml Grey top tube
- Cryo-label sheet to paste on the tubes
- Standard 22 gauge blood collection needle with holder
- Alcohol wipes
- Cotton pads
- Band-Aids

- Holding rack for Vacutainers
- Sharps needle disposal units (sharps container)
- Drape sheets to cover work surface (Chux)
- Laboratory coat and gloves
- Tourniquet

Procedures for blood collection:

Steps to be followed for sample collection -

i. Ask the participant when s/he last ate a meal and record the time on the Blood Collection Form.

ii. Before the blood samples are drawn, make the participant sit or recline on a chair for at least five minutes and remain in this position during the venipuncture.

iii. Record the time of the blood collection on the Blood Collection Form.

iv. Clothing should not restrict the arm. Ask the participant to adjust her/his clothing to expose the middle portion of her/his arm.

v. Explain the procedure and position the participant with the arm in a dependent position.

vi. Prepare the appropriate blood collection tubes, placing them in a test tube rack in the order in which they will be drawn.

vii. Wash your hands and put on protective gloves.

viii. Position the participant's arm so that the veins are readily accessible and you are able to work in a comfortable position. Ensure that the arm is in a downward position with the elbow lower than the heart to prevent backflow. Inspect the arm to be used for the venipuncture. The veins of choice are those located in the antecubital area.

ix. Blood should not be drawn from any arm with an arterial access, such as a fistula or shunt, nor from any arm which has a rash or open sore or is swollen or edematous.

x. Apply a tourniquet four to five inches above the site with enough pressure to impede venous blood flow. Select a vein that is palpable and well-fixed to surrounding tissue.

xi. Clean the skin with alcohol in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area already cleansed. Dry the area completely using a sterile gauze pad before the venipuncture in order to reduce the burning sensation caused by alcohol penetrating the skin.

xii. Perform the blood draw by inserting an appropriate needle into the arm, then attaching the Vacutainer tube.

xiii. Immediately after the venipuncture, press a clean gauze square over the venipuncture site. After a few minutes, check the venipuncture site and if clotting has occurred, apply an adhesive bandage over the gauze pad. If bleeding continues, apply direct pressure to the site for five minutes.

xiv. After the blood draw is complete, fill in the appropriate items in the Blood Collection Form.

xv. If the blood draw is not successfully completed for all tubes (all tubes filled to capacity), another draw should be attempted from the other arm. If attempts from both arms are unsuccessful, no further attempts should be made to collect the specimen.

Venipuncture complications

Hematosis

Hematomas are a common complication of venipuncture that is caused by coagulation of extravasated blood in a tissue or cavity. Hematomas most frequently result from failure to apply pressure, insufficient time spent in applying the pressure, or from flexing the arm to stop bleeding. Once the venipuncture is complete, instruct the participant to apply mild pressure to the puncture site and raise her/his arm straight in the air for about two minutes. Constant pressure should always be maintained until the bleeding stops.

Syncope (Fainting)

Syncope or fainting is a sudden loss of strength or temporary loss of consciousness and is caused by decreased blood flow to the brain. To prevent injury of any participant who might faint, always perform the venipuncture when the participant is in a seated, relaxed position with feet flat on the ground.

The warning signs include becoming pale and beginning to perspire heavily, feeling dizzy and hot, beginning to pant (hyperventilate), and/or feeling nauseated.

The participant should always be instructed not to watch the procedure. If the participant displays any of the above signs, immediately terminate the venipuncture. The seated participant should put her/his head down between her/his knees, and prevent the participant

from falling. Talk to the participant in a calm, reassuring manner, instruct the participant to take slow deep breaths and call for a family member, if available. If the participant faints, gently ease the participant to a lying position and elevate her/his feet. Check the radial pulse. After the participant regains consciousness, give her/him some glucose drink or fruit juice. Stay with the participant until s/he has recovered.

Continued bleeding

Some participants may be receiving certain drug therapies or have bleeding disorders that may cause them to continue to bleed after the venipuncture. It may be necessary to apply pressure to the puncture site for an extended period of time. If the participant continues to bleed after ten minutes call the Research Officer (medical doctor).

Thrombosis

Thrombosis is the formation of blood clots (thrombi) inside a blood vessel or inside the chambers of the heart. They can occur as a result of venipuncture when the endothelial lining of the vein is injured. A thrombosed vein should not be used for venipuncture. A thrombosed vein can be detected by palpation prior to the venipuncture. A vein with thrombosis lacks resilience, feels hard and cordlike, and rolls easily.

Accidental Needle Stick or Contamination of Open Wound (of Phlebotomist)

Accidental needle sticks or contamination of an open wound can occur as a result of careless technique and improper disposal of used needles and blood drawing equipment. If an accidental needle stick injury occurs, wash the area thoroughly with soap and water, cover it, and report the incident immediately to the field supervisor. Refer to hospital/center policies for completing the required documentation, instructions, and proper post needle stick injury procedures.

Packing instructions for samples following blood collection

Samples should be placed in the racks inside ice buckets to minimize exposure to sunlight and maintain an even temperature. Open the buckets as little as possible. The ice buckets should have icepacks at the bottom and on the sides.

Recommendation

Bring extra buckets with extra ice packs. If the ice packs in the first bucket do not maintain a sufficiently cool temperature, move the specimens into the second bucket with frozen packs or add fresh ice packs to the original bucket to maintain the appropriate temperature.

Specimen Processing

After the blood specimens have been collected place the pre-labeled vacutainers inside the ice buckets. The specimen should be processed within 20-30 minutes of collection in the blood camp itself (Transfer the ice buckets with samples to the laboratory for processing as soon as possible)

Labeling of cryovials

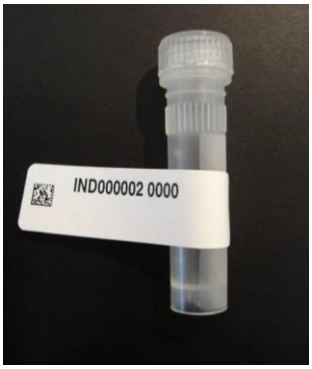

Table: Overview of aliquots to be prepared

Tubes and their aliquots	**No. of aliquots**
Red top- Serum	**3 + 1**
Lavender Top – Whole blood (for Hemoglobin analysis)	**1***
Lavender Top – Whole blood (for HbA1c analysis)	**1**
Lavender Top – EDTA Plasma	**3**
Lavender Top – Buffy Coat	**1**
Lavender Top – RBC	**2**
Grey Top- Plasma	**2 + 1***
Urine samples	**3 + 1**

***to be transported to local lab**

Processing for Red top tube

i. Allow the tubes to remain upright at room temperature for complete blood coagulation. Once clot retraction is complete, maintain the red-top tube at 2° to 8° C by placing the tube upright in a test tube rack stored in either a refrigerator or an ice water bath if needed until it can be centrifuged.
ii. Label the cryovials (four 2.0 ml vials for serum) with participant ID.
iii. Centrifuge the red top tubes for 10 minutes at 3,500 rpm.
iv. After the blood has been centrifuged, reserve 150 µl for clinical tests in one cryovial (**S5**).
v. Aliquot the remaining serum from the red-top tube into three pre- labeled cryovials (**S1, S2, S3 & S4**). Aspirate all the serum generated into the tube.

Prepare an additional aliquot of serum for every tenth sample collected for blinded duplicate analysis. The person processing the sample will be provided with an additional sequence of numbering which would be generated by the Biochemistry in-charge. The technician analysing the samples will be blinded for these numbers.

vi. Discard the clot.

vii. Store the vials **S1** into **Box A, S2 into Box B, S3 into Box C** and **S4** into **Analysis Box**.

viii. Store the boxes in deep freezer at -80° C.

Processing for Lavender top tube

i. Label the cryovials (three vials for plasma, two vials for whole blood, one vial for buffy coat and two vials for RBC with specimen ID labels.

ii. Mix the content of the tube by inverting it 6-7 times. Remove 100 µl of whole blood from the lavender top tube in a separate cryovial (**WB**) for Hb A1c analysis.

iii. Take out 20 ul of whole blood and estimate haemoglobin or transfer 50 ul in a tube for the purpose.

iv. Centrifuge lavender top tube for 10 minutes at 3,500 rpm.

v. Aliquot plasma into three cryovials (**EP1, EP2** & **EP3**).

vi. Transfer the buffy coat into one cryovial (**BC**).

vii. Wash RBCs three times with saline (0.9% sodium chloride).

viii. For this add same amount of saline into the tube. Mix gently by inversion. Centrifuge. Discard the supernatant. Repeat once more using saline. The final supernatant should be clear with no colour. **DO NOT USE DISTILLED WATER FOR WASHING AS IT WILL HEMOLYZE RED BLOOD CELLS**.

ix. Transfer RBCs into labeled cryovials (**RBC1 & RBC2**).

x. In order to maximize the buffy coat yield, when removing plasma leave a small amount of plasma above the buffy coat and when aspirating buffy coat include a small amount of RBC in the sample.

xi. Transfer all the plasma into the cryovials. Do not discard any component of lavender top tube.

xii. Divide the participant's plasma, RBC, and buffy coat vials between labelled and numbered freezer boxes. Place the **EP1** vials in **Box-D**, **EP2 vial into Box E and EP 3 vial into Box F**. Place vial with buffy coat (**BC**) in **Box-G**, **RBC1 into Box H & RBC2** in Box **I.**

xiii. Store the boxes in a deep-freezer at -80° C.

Processing for Grey top tube

i. Label the cryovials (three vials for plasma) with specimen ID labels.

ii. Centrifuge lavender top tube for 10 minutes at 3,500 rpm.

iii. Transfer 100 µl of plasma in one cryovials (**P3**) and the rest of the plasma into two cryovials (**P1 & P2**). Use cryovial (**P3**) for clinical tests in the local laboratory and store cryovial **P1** in deep- freezer in **Box J and P2 in Box L.**

Prepare an additional aliquot of plasma for every tenth sample collected for blinded duplicate analysis. The person processing the sample will be provided with an additional sequence of numbering which would be generated by the Biochemistry in-charge. The technician analysing the samples will be blinded for these numbers.

iv. Discard the packed cells.

v. Store the boxes in a deep freezer at -80° C.

Urine specimen

Collection procedure: One early morning void mid-stream urine will be collected from all participants. A sterile container labelled with the participant ID should be provided to all participants during visit one. Explain to the participant that s/he has to collect an early morning void on the day of visit (mention the day/date of visit) and the container has to be at least three-fourth filled. During visit confirm whether the sample collected in the container by the participant is the morning void of the same day. If the sample is not the morning void of the same day or there is any other problem, then provide another sterile container labelled and repeat the instructions. Re-visit the participant on the following day to collect the sample.

Transportation

The container with sample has to be carried to the lab. in ice-bucket then needs to be deposited at the laboratory for processing.

Processing of urine

Label three cyovials with participant ID. Transfer urine into 2.0 ml of urine into the cryovials (**U1, U2, U3 & U4**). Use the remaining urine in the container to test for protein and sugar content using dipsticks. Store **U1, U2 & U3 in Box K and place into the** deep - freezer at -80° C. Store **U4 into Analysis box**.

Storage of Specimens

Table: Storage of Aliquots has to be done as per details given in the table

Box A	**S1**
Box B	**S2**
Box C	**S3**
Box D	**EP1**
Box E	**EP2**
Box F	**EP3**
Box G	**BC**
Box H	**RBC1**
Box I	**RBC2**
Box J	**P1**
Box K	**U1, U2, U3**

Box L	**P2**
Analysis Box for Delhi	**S4, WB, & U4**
For local laboratory	**P3 (Glucose),** **Hb (Hemoglobin)**

Labeling the cryoboxes:

Arranging the cryovials: The cryovials are arranged in the cryoboxes (A,B,C, D, E --- L) The lay-out of each cryobox should be prepared in an excel sheet indicating the number of vials stored with the sample ID and the amount of processed material in each vial. Example of lay-out of cryobox D-001 is shown below.

Example: Layout of Cryovials in cryobox D-001

	Box D-001		
Position No.	**Sample no.**	**details**	**volume**
1	Participant ID	EP1	500
2	Participant ID	EP1	600
3	Participant ID	EP1	200

4	Participant ID	EP1	300
5	Participant ID	EP1	500
6	Participant ID	EP1	200
-			
-			
81	Participant ID	EP1	500